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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,895	11/30/2001	David Samuel Cohen	111465.127	4229

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EXAMINER

SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,895

Applicant(s)

COHEN, DAVID SAMUEL

Examiner

Samuel P. Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,14-27,30-35 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,14-27,30-35 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11-12,14-27,30-35,58-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear and indefinite to claim a position of the separation chamber by a first and a second portions in relation to the antechamber.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-12,14-27,30-35,58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (USPN 6,063,589).

Kellogg discloses a method and apparatus for performing microanalytic analyses on a platform by rotation, thereby utilizing the centripetal forces resulting from rotation of the platform to motivate fluid movement through microchannels embedded in the microplatform.

Kellogg discloses an optical bio-disc that comprises:

- substrate (col. 8, lines 6-38) having encoded information being readable by a disc drive assembly to control rotation of the disc (col. 8, line 37-col. 9, line 20);
- antechamber (fig 8-9H; entry port 401, antechamber);
- separation chamber in fluid communication with the antechamber (403 see figure 9G, col. 18, lines 52-60);
- fluid output port (406) located between the first and second portions of the separation chamber at a position selected to permit outward transmission therethrough of a liquid component which also permits fluid flow of the plasma fraction therethrough (col. 18, lines 5-24, col. 18, lines 52-60);
- metering capillary (406 and 408,col. 18, lines 5-24) the outlet port turns into a metering capillary because it only allows the plasma fraction to pass through (see Fig 9H where a metered amount of plasma fraction is passed, shown as larger diagonal lines);
- assay zone in fluid communication with the metering chamber so that when a sample is deposited in the antechamber and a rotation is applied, a metered amount of a liquid component is moved to the assay zone (col., lines 5-21).

- waste chamber (404) that is in fluid communication with both the metering chamber (fig. 8-9H).

The assay chamber includes optical detection of the reaction that occurs in the assay (col. 14, lines 6-35; col. 17, lines 5-21). With regards to claim 14, a disk drive is not claimed, and is not attributed patentable weight, even though Kellogg teaches a read head (col. 14, lines 6-34; col. 9, lines 16-20). Throughout Kellogg there are multiple embodiment which cover all the limitations of claimed subject matter in the instant application. With respect to claims 16-27 and 30-35, it is noted that Applicant recites limitation on the manner in which the biodisk is used. Such limitations are not attributed patentable weight in claims to the device. It is also noted that Kellogg teaches a process in which incorporates the steps recited in these claims. Kellogg discloses that samples to be used in this apparatus comprise blood, plasma, serum, lymph, saliva, tears, cerebrospinal fluid, urine, sweat, plant and vegetable extracts, semen and as cites fluid and does not limit just to these specific examples (col. 6, lines 1-6). Kellogg also discloses a process of using an optical biodisc for separating, metering and analyzing a biological sample (col. 12, line 1 –col. 14, line 38). Kellogg discloses that the platform shown in Fig. 9a through 9H is for separating plasma from whole blood. Then analysis of the components in the sample are analyzed (col. 14, lines 6-34).

Kellogg discloses “disks of the invention are fabricated with an injection molded, optically clear base layer having optical pits in the manner of a conventional compact disk (CD). The optical pits provide means for encoding instrument control

programming, user interface information, graphics and sound specific to the application and driver configuration.” It is clear from this statement that the disc is encoded with control programming for controlling the rotation of the disc. It is also well known in the art that these types of bio-discs have rotation information encoded on the bio-disc itself that can be read by a reader similar to a CD reader.

Response to Arguments

Applicant's arguments filed 5/24/05 have been fully considered but they are not persuasive.

Applicant argues, “Applicant disagrees that such a feature is taught or suggested by this reference, particularly with regard to encoded information directed to control rotation of the disc.” Kellogg discloses “disks of the invention are fabricated with an injection molded, optically clear base layer having optical pits in the manner of a conventional compact disk (CD). The optical pits provide means for encoding instrument control programming, user interface information, graphics and sound specific to the application and driver configuration.” It is clear from this statement that the disc is encoded with control programming for controlling the rotation of the disc. It is also well known in the art that these types of bio-discs have rotation information encoded on the bio-disc itself that can be read by a reader similar to a CD reader.

Applicant argues, “Applicant again notes that there is no discussion as to the metering of the flow, or of the control of amounts of fluid to be moved.” As seen in fig.

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9G there is a cut off point where excess sample is over flowed into the waste chamber 404 and the plasma fraction (located on top, indicated by the large spaced lines) flows into the outlet port located radially outward of the separation chamber. The plasma fraction is metered because only the plasma fraction that is located in the separation chamber after the excess is overflowed in the waste chamber is allowed to flow into the outlet port and through the metering capillary 406 and 408. Even if the flow of plasma in the chamber 405 results from the fluid flow overcoming the capillary barrier 407 by rotation at a third rotational speed, only the plasma above the outlet port goes through the capillary 406 and 408 (see fig 9g to 9H), which is specifically the function of a metering capillary, to set a cut of point where no more liquid can flow through.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



June 22, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700